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EXAMINER

BAGGOT, BRENDAN O

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/647,140	Applicant(s) HAKE ET AL.	
	Examiner Brendan O. Baggot	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 45-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>14 April, 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction / Election

1. The Office acknowledges the receipt of Applicant's restriction election, filed 24 April 2006. Applicant elects Group I, claims 1-44, drawn to suppressing seed-oil biosynthesis, carbonic anhydrase, DGAT, and RNAi without traverse. Claims 1-87 are pending. Claims 45-87 are withdrawn. Claims 1-44 is/are examined in the instant application.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This restriction is made FINAL.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See M.P.E.P. § 608.01. See page 60, for example.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's 11 page IDS filed 14 April, 2005, is attached to the instant Office Action. Reference 5I, by Oliver was not provided and has been lined through. Duplicate copies of reference 5W by Shintani were provided.

4. It is desirable to avoid the submission of long lists of documents –for example the approximately 2,490 pages of art submitted by Applicant – if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information – including the submission of duplicate copies of references – for example. If a long list is submitted, highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most significance. See MPEP § 2004, para. 13; See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F. Supp. 948, 175 USPQ 260 (S.D. Fla. 1972), *aff'd*, 479 F.2d 1338, 178 USPQ 577 (5th Cir. 1973), cert. denied, 414 U.S. 874 (1974). *But cf. Molins PLC v. Textron Inc.*, 48 F.3d 1172, 33 USPQ2d 1823 (Fed. Cir. 1995).

Drawings

5. The drawings are acceptable for examination.

Claim Objections

6. Claim 24 is objected to because of the following informalities: "Clam" is misspelled.

7. In Claim 18, "CA gene" should be defined as carbonic anhydrase before being used as an abbreviation.

8. Claim 5 recites the limitation "said cotton plant". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 U.S.C. §112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 24-25, 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 24-25, 43 are rejected as lacking an adequate written description regarding the RNAi oligonucleotides which function to suppress seed-oil biosynthesis by affecting early or late gene, including DGAT or CA genes, expression and activity.

Applicant broadly claims any "reduced seed-oil content plant . . . [expressing a transgene] wherein said seed-oil suppressing transgene is a nucleic acid that encodes any RNAi sequence for a gene that is early in the seed-oil biosynthesis pathway and for a gene that is late in the seed-oil biosynthesis pathway" (claim 24). This seed-oil biosynthesis pathway "RNAi sequence" is CA or DGAT. (claim 25)

Applicant describes RNAi strategies known to those skilled in the art. (para. 49).

While RNAi strategies are known, the specific 20-30 nucleotide RNAi sequence specific for DGAT or CA to be used to down regulate seed-oil biosynthesis is not known nor is it described by applicant.

Applicant does not describe any RNAi sequences which are specific for DGAT or CA, which have the art recognized physical structure of RNAi molecules. Furthermore, Applicant does not describe which portions of the DGAT and CA genes would not form the proper structure for effective seed-oil biosynthesis suppression. Applicants are invited to point to the line and page number which goes beyond the mere recitation of a gene sequence which is to be targeted and provides the actual description of an operative, fully described RNAi molecule. Merely providing the sequence of the target gene is not a description of the RNAi sequence to be used. In a technical discipline which requires specific sequences for function, the artisan would not be able to envision the specific 20-30 nucleotide RNAi sequence specific for DGAT or CA and, therefore, would not conclude that applicant was in possession of the invention as claimed at the time the specification was filed.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the

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absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. *See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at

1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by “its physical or chemical properties” (e.g. a DNA sequence).

Given the lack of written description of the sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products

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including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described.

Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See The Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

10. Claims 1-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cotton varieties DP 555 BG/RR and DP 493 does not reasonably provide enablement for transformed plants or plant parts, elite or primitive cultivars, seed oil suppressing genes, mutants, including ethyl methanesulfonate (ems) mutants, or transgenic plants or plant parts with suppressed seed oil storage, a mutagenized seed stock, mutants or transgenic plants or plant parts expressing any gene or transgene, including diacylglycerol acyltransferase (DGAT) or carbonic anhydrase (CA), early or late genes or transgenes, suppressing or not suppressing of seed-oil biosynthesis or early or late genes thereof, suppressing any biosynthetic step in oil biosynthesis, including via an RNAi mechanism, via any promoter or chimeric promoter, via any promoter activated by external stimuli, via any promoter activated by copper, benzene sulfonamide herbicide safener, glucocorticosteroid hormone, estradiol, or ecdysteriodial, any promoter which remains on after activation, a reduced seed-oil content plant with 1% to 17% seed oil content of the fuzzy whole seed weight, any plant with stably increased sucrose pools, plurally mutagenized or plurally transformed plants, including plants transformed with one or

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more RNAi sequence(s) specific for an early or late gene or genes, including CA or DGAT genes.

The *Wands* court set forth the enablement test:

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the 'claims.'"

M.P.E.P. § 2164.01(a)

The claims are broadly drawn to transformed plants, plant cells, plant parts, elite or primitive cultivars, seed oil suppressing genes, mutants, with suppressed seed oil synthesis, a mutagenized seed stock, mutants or transgenic plants or plant parts expressing any gene or transgene, including diacylglycerol acyltransferase (DGAT) or carbonic anhydrase (CA), early or late oil biosynthetic pathway genes or transgenes, suppressing or not suppressing of seed-oil biosynthesis, suppressing any biosynthetic step in oil biosynthesis, including via an RNAi mechanism, using a constitutive or tissue specific promoter or chimeric promoter, a reduced seed-oil content plant with 1% to 17% seed oil content of the fuzzy whole seed weight, and/or with stably increased sucrose pools, including plurally mutagenized or plurally transformed plants, and plants transformed with one or more RNAi sequence(s) specific for an early or late gene or genes, including CA or DGAT genes.

Applicants teach cotton varieties DP 555 BG/RR and DP 493.

Applicants do not teach transformed plants or plant parts, elite or primitive cultivars, seed oil suppressing genes, mutants, including ethyl methanesulfonate (ems) mutants, or transgenic plants or plant parts with suppressed seed oil storage, a mutagenized seed stock, mutants or transgenic plants or plant parts expressing any gene or transgene, including diacylglycerol acyltransferase (DGAT) or carbonic anhydrase (CA), early or late genes or transgenes, suppressing or not suppressing of seed-oil biosynthesis or early or late genes thereof, suppressing any biosynthetic step in oil biosynthesis, including via an RNAi mechanism, via any promoter or chimeric promoter, via any promoter activated by external stimuli, via any promoter activated by copper, benzene sulfonamide herbicide safener, glucocorticosteroid hormone, estradiol, or ecdysteriodial, any promoter which remains on after activation, a reduced seed-oil content plant with 1% to 17% seed oil content of the fuzzy whole seed weight, any plant with stably increased sucrose pools, plurally mutagenized or plurally transformed plants, including plants transformed with one or more RNAi sequence(s) specific for an early or late gene or genes, including CA or DGAT genes.

The Nature Of The Invention

The claims are drawn to mutants or transformed plants. The invention is a class of inventions which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The Breadth Of The Claims

The claims broadly encompass any transformed or mutagenized plant, including singly or plurally mutagenized or transformed plants, transformed or mutagenized at any gene locus, any and all exemplified and nonexemplified genes, including those genes which are known to have no effect on plant seed oil biosynthesis. The broad language expressly includes any gene because any and all genes directly or indirectly affect seed-oil biosynthesis suppression.

Quantity Of Experimentation

The quantity of experimentation in this area is large since the oil pathway is interlinked to the carbohydrate and protein pathways and draws and feeds precursors and metabolites from and thereto respectively. The amount of experimentation necessary to solve the problems associated with oil pathway manipulation, including oil biosynthesis suppression via either mutagenesis or genetic recombination is very substantial, requiring extensive experimentation. This effort is an inventive, unpredictable and difficult undertaking in itself. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Voelker et al., teaches that the quantity of experimentation for oil pathway manipulation can involve intensive research in several laboratories and yet remain elusive for some time. (Voelker, et al (2001) Plant Mol. Biol. 52, 335–361, p. 340, first full parag.).

The Unpredictability Of The Art And The State Of The Prior Art

There is abundant prior art to suggest that oil pathway manipulation, including suppression of seed-oil biosynthesis is difficult, unpredictable and unsuccessful. A recent review by Voelker details a variety of problems seen in oil pathway manipulation. As of the filing date of the application, it was even less predictable and more experimental than shown by Voelker as discussed supra. (*Id.*).

Rohr et al., teach that RNAi, in a number of eukaryotes, is *unpredictable*, that the level of silencing triggered by dsRNA-producing transgenes is *quite variable* depending on the type of construct, transgene copy number, site of integration, and target gene (references omitted), and that the use of inhibitory RNA (IR) constructs containing introns appears to improve their effectiveness (references omitted) but independent transgenic lines still show variable phenotypes and degrees of target mRNA decrease (references omitted) (emphasis added).

Rohr continues that in *Arabidopsis thaliana* reduction in transcript levels induced by IR transgenes appears to *differ significantly among target genes* (references omitted). Thus, individual lines *need to be molecularly characterized by burdensome trial and error experimentation* for suppression of a certain gene before potential phenotypic defects can be evaluated (emphasis added). (ROHR ET AL., (2004) The Plant Journal, 40:611-621).

Working Examples

The specification has no working examples of singly or plurally recombinant plants, how to make and use such plants, or how to make and use singly or plurally mutagenized plants any of which having the Claimed compositions.

Guidance In The Specification.

The specification, while suggesting the use of the seed-oil suppressing genes, including providing examples of CA and DGAT, did not provide significant guidance on how to overcome art recognized problems in identifying which genes would yield the desired compositions without undue trial and error experimentation. Applicant provided no guidance on how to select which genes to mutate or even which mutated or recombinant genes will achieve the desired goal. While the ordinarily skilled artisan can readily make mutants using ems mutagenesis, one would not know which mutants to make, how to rule out mutants which would not work without first making them and testing them, nor how to eliminate other problems caused by making such mutants. Applicant provided no guidance on how to eliminate problems associated with making changes which lead to lethal phenotypes.

Level Of Skill In The Art

The level of skill in the art is deemed to be high.

Therefore, given the unpredictability of the genetic engineering of plants for the production of decreased levels of seed-oil; the lack of working examples other than that Delta and Pineland commercial cultivars DP 555 BG/RR and DP 493; the relatively small amount of guidance in the specification with regard to the seed-oil biosynthetic mutant production or the seed-oil biosynthetic transgenic plant production using non-exemplified RNAi constructs and given the breadth of the claims which encompass any transformed or mutagenized plant, including singly or plurally mutagenized or transformed plants, transformed or mutagenized at any gene locus from any plant species and having any reduced seed-oil biosynthetic phenotype; and given the state of the art which showed limited success in other plant species balanced only against the high skill level in the art, it is concluded that it would require undue experimentation for one of skill in the art to make the plant cells and plants of the claims as broadly written.

Claim Rejections - 35 U.S.C. §112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2, 17, 18, 23, 24, 25, 32-35, 43-44 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

12. The term "a gene early in the oil biosynthetic pathway" is indefinite in that it is unclear where the beginning of the oil biosynthetic pathway is. Moreover, the term early is indefinite and no reference point for comparison has been provided.

13. The term "a gene late in the oil biosynthetic pathway" is indefinite in that it is unclear where the beginning of the oil biosynthetic pathway is. Moreover, the term late is indefinite and no reference point for comparison has been provided.

14. Regarding Applicants recitation of "external stimulus," even though examples are given (See Spec. parag. 20), it is unclear how external stimulus is defined or what the metes and bounds of external stimulus are.

15. Claim 2 for example contains the trademark/trade name Canola. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe Brassica species including *B. napus*, *B. campestris* and *B. rapa* and, accordingly, the identification/description is indefinite. All subsequent recitations are similarly indefinite.

16. Claim 5 recites the limitation "said cotton plant." There is insufficient antecedent basis for this limitation in the claim.

Clarification and/or correction are required.

Claim Rejections - 35 U.S.C. §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1-2, 4, 6, 9-11, 15-16, 19-22, 26, 29, 31, 36, 38, 41-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Lassner et al (issued 9/3/02, 6444876-US-B1, filed June 4, 1999).

Applicant broadly claims transformed plants or plant parts, elite or primitive cultivars, seed oil suppressing genes, mutants, including ethyl methanesulfonate (ems) mutants, or transgenic plants or plant parts with suppressed seed oil storage, a mutagenized seed stock, mutants or transgenic plants or plant parts expressing any gene or transgene, including diacylglycerol acyltransferase (DGAT) or carbonic anhydrase (CA), early or late genes or transgenes, suppressing or not suppressing of seed-oil biosynthesis or early or late genes thereof, suppressing any biosynthetic step in oil biosynthesis, including via an RNAi mechanism, via any promoter or chimeric promoter, via any promoter activated by external stimuli, via any promoter activated by copper,

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benzene sulfonamide herbicide safener, glucocorticosteroid hormone, estradiol, or ecdysteriodial, any promoter which remains on after activation, a reduced seed-oil content plant with 1% to 17% seed oil content of the fuzzy whole seed weight, any plant with stably increased sucrose pools, plurally mutagenized or plurally transformed plants, including plants transformed with one or more RNAi sequence(s) specific for an early or late gene or genes, including CA or DGAT genes.

Lassner teaches a reduced seed-oil content plant cell (See claim 10, 11, 12), including cotton, corn, soybean, wheat, or canola (Claim 15), that expresses a seed-oil suppressing transgene (See Claims 6, 12, 14, 26, 32), under control of a plant-active promoter that would express in germplasm (i.e. embryo) (See Claim 31) wherein said plants exhibited a reduction in seed-oil biosynthesis and a concomitant increase in plant carbohydrate or both and wherein said seed-oil suppressing gene is antisense DGAT (See Claims 6, 11, 12, 14, 26, 32).

Because of the interconnected nature of the oil and carbohydrate pathways, where oil is reduced as described in Lassner, carbohydrates would inherently be increased due to increased availability of carbon skeletons, increased source strength available to all pathways in the plant, and the natural ability of plants to maintain homeostasis by shunting excess metabolites from one substrate pool to another.

Canola is interpreted to mean any *Brassica* family member and is known to encompass varieties such as *B. napus*.

Thus the reference teaches all the limitations of Claims 1-2, 4, 6, 9-11, 15-16, 19-22, 26, 29, 31, 36, 38, 41-42.

Claim Rejections - 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lassner et al (9/02, 6444876-US-B1) in view of Auld et al., (1998) Proceedings of the Belt wide Cotton Conf, 1 :550-552) and further in view of Dudley et al (1992) Maydica 37:81-87).

Applicant broadly claims transformed plants or plant parts, elite or primitive cultivars, seed oil suppressing genes, mutants, including ethyl methanesulfonate (ems) mutants, or transgenic plants or plant parts with suppressed seed oil storage, a mutagenized

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seed stock, mutants or transgenic plants or plant parts expressing any gene or transgene, including diacylglycerol acyltransferase (DGAT) or carbonic anhydrase (CA), early or late genes or transgenes, suppressing or not suppressing of seed-oil biosynthesis or early or late genes thereof, suppressing any biosynthetic step in oil biosynthesis, including via an RNAi mechanism, via any promoter or chimeric promoter, via any promoter activated by external stimuli, via any promoter activated by copper, benzene sulfonamide herbicide safener, glucocorticosteroid hormone, estradiol, or ecdysteriodial, any promoter which remains on after activation, a reduced seed-oil content plant with 1% to 17% seed oil content of the fuzzy whole seed weight, any plant with stably increased sucrose pools, plurally mutagenized or plurally transformed plants, including plants transformed with one or more RNAi sequence(s) specific for an early or late gene or genes, including CA or DGAT genes.

Lassner teaches a reduced seed-oil content plant cell (See claim 10, 11, 12), including cotton, corn, soybean, wheat, or canola (Claim 15), that expresses a seed-oil suppressing transgene (See Claims 6, 12, 14, 26, 32), under control of a plant-active promoter that would express in germplasm (i.e. embryo) (See Claim 31) wherein said plants exhibited a reduction in seed-oil biosynthesis and a concomitant increase in plant carbohydrate or both and wherein said seed-oil suppressing gene is antisense DGAT (See Claims 6, 11, 12, 14, 26, 32).

Lassner does not teach mutagenesis or breeding of untransformed plants except with transformed plants.

Auld teaches untransformed plant mutagenesis and that methods (p. 550, right Col., 3rd full para.) of elite (p. 550-552) cotton native-gene mutagenesis (p. 550, left Col.), including ems and random mutagenesis (p. 550-552), “. . . can have . . . [a tremendous] . . . impact on developing new genes that enhance the fiber and other economically important traits of cotton (*Gossypium hirsutum* L.) . . .” (See Abstract, p. 550, left Col. 1st para.).

Dudley teaches untransformed plant breeding and that decreasing TAG and oil content would increase flow away from lipids and towards carbohydrate in plant seeds.

“Selection for either protein or oil has resulted in changes in percent starch as would be expected given that starch is the largest component of the kernel and thus is the component most likely to be affected by a change in either protein or oil.

In general, changes in % starch per percentage point change in oil were higher than changes per percentage point protein. Given that oil is higher in caloric value than protein, this difference might be expected.”
(Dudley, (1992) See p. 87, left Col. 1st and 2nd para.).

It would have been obvious at the time of invention to modify the invention of Lassner to substitute cotton for *Brassica* in an antisense method of transformation with a DGAT coding sequence to reduce oil content; or to substitute alternatively mutagenesis of cotton in order to increase fiber yield as taught by Auld for a method of transforming cotton with a DGAT coding sequence. One of ordinary skill in the art would have been motivated by the knowledge common in the art that a method of either mutagenizing CA or DGAT or transforming a plant with an antisense DGAT coding sequence both to reduce CA or DGAT's expression would reduce TAG and oil content

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and that decreasing TAG and oil content would increase flow away from lipids and towards carbohydrate in plant seeds as taught by Dudley; and that methods of mutagenesis would be useful in the in the area of biotechnology for increasing fiber yield in cotton also taught by Auld; and that one would have a reasonable expectation of success of making and selecting transformed or mutagenized cotton plants having suppressed seed oil and/or enhanced fiber yield given the teachings of Lassner for reducing TAG and of the success of Auld in using EMS mutagenesis to increase fiber length in cotton; wherein an elite or primitive cotton cultivar plant is transformed using either antisense or RNAi or chemically or randomly mutagenized in some unspecified fashion having either increased fiber yield and/or suppressed seed oil content in the seed is obvious given the lack of criticality.

Further, the choice of a constitutive, seed specific, chimeric, inducible/repressible (i.e. activated by an external stimulus with or without an excisable blocking sequence), or the cotton AGP promoter and the choice to further include suppression of carbonic anhydrase in the transformed or mutagenized plant or plant seed is an obvious experimental design choice absent any evidence of criticality.

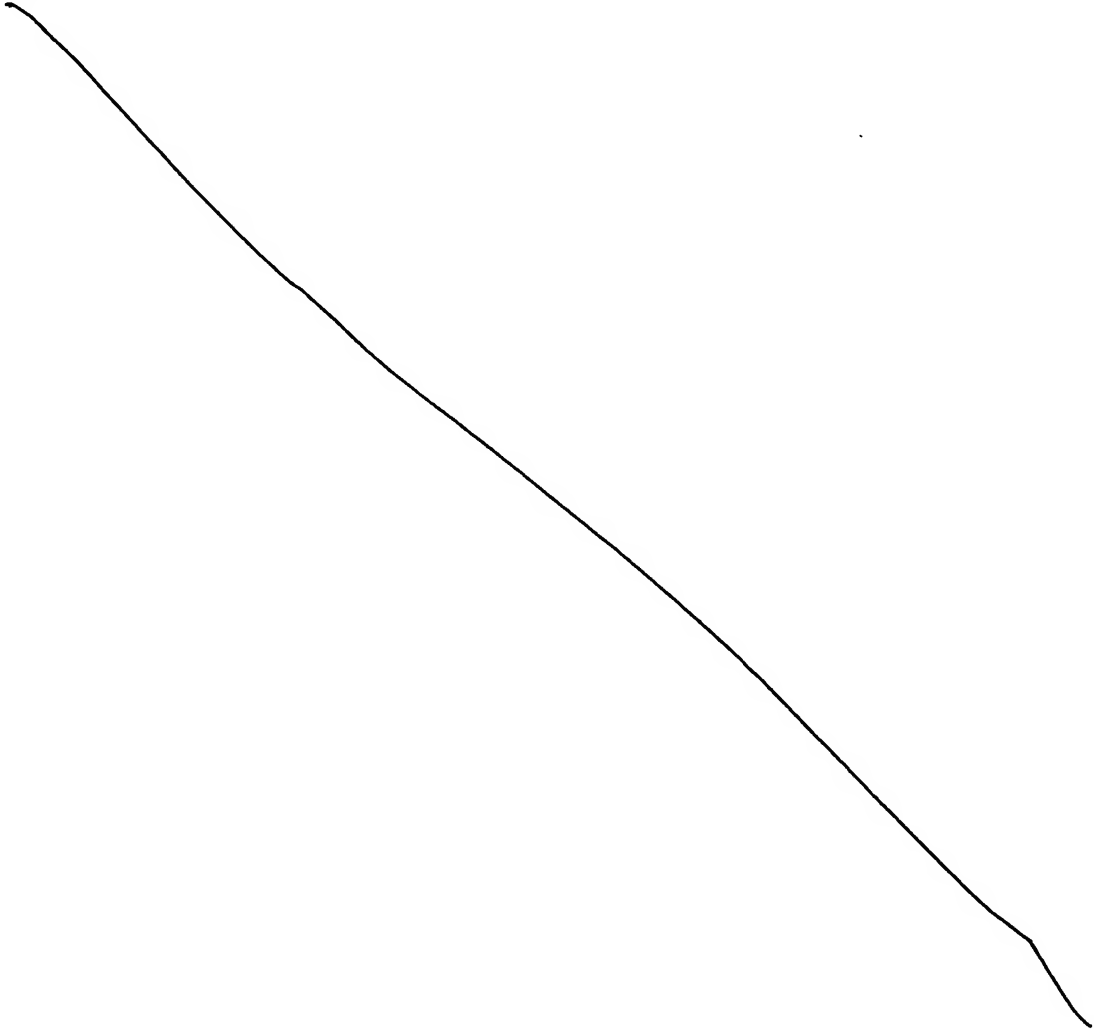
Accordingly, one of skill in the art would have been motivated to generate the invention of Claims 1-44.

Remarks

20. No Claim is allowed.

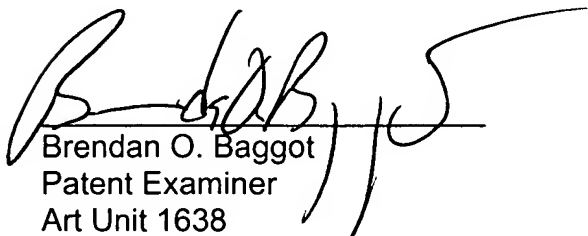
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



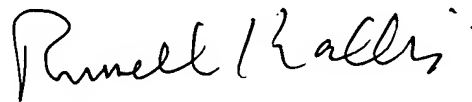
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Brendan O. Baggot
Patent Examiner
Art Unit 1638

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER



bob